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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,358	10/02/2003	Karine Vidal	112843-076	8288
29157	7590	09/24/2009	EXAMINER	
K&L Gates LLP			KAM, CHIH MIN	
P.O. Box 1135			ART UNIT	
CHICAGO, IL 60690			PAPER NUMBER	
			1656	
			NOTIFICATION DATE	
			DELIVERY MODE	
			09/24/2009	
			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/676,358	<b>Applicant(s)</b> VIDAL ET AL.	
	<b>Examiner</b> CHIH-MIN KAM	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 May 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-20 and 23-28 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18, 20 and 25-27 is/are allowed.
- 6) ☒ Claim(s) 17, 19, 23, 24 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 12-20 and 23-28 are pending.

Applicants' amendment filed May 29, 2009 is acknowledged. Applicant's response has been fully considered. Claims 17 and 28 have been amended, and claims 21-22 have been cancelled. Claims 12-16 are non-elected inventions and withdrawn from consideration. Therefore, claims 17-20 and 23-28 are examined.

### **Claim Objections**

2. The previous objection to claim 22 is withdrawn in view of applicants' cancellation of the claims in the amendment filed May 29, 2009.

### **Withdrawn Claim Rejections - 35 USC § 102**

3. The previous rejection of claim 17 under 35 U.S.C. 102(b) as being anticipated by Takada *et al.* (EP 0786473), is withdrawn in view of applicants' amendment to the claims, and applicant's response at pages 6-9 in the amendment filed May 29, 2009.
4. The previous rejection of claim 21 under 35 U.S.C. 102(b) as being anticipated by Goto *et al.* (EP 0816380), is withdrawn in view of applicants' cancellation of the claims, and applicant's response at page 6 in the amendment filed May 29, 2009.

### ***New Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1656

5. Claims 17, 19, 23, 24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Ostillo *et al.* (Clinical and Experimental Immunology 104, 543-546 (June 1996); listed in PTO-892 of 7/28/05) as evidenced by US 2004/0137074.

Examiner has given the broadest reasonable interpretation to the claims (i.e., claims 17, 19, 23, 24 and 28) that refer to a food material, enteral composition or pharmaceutical composition, comprising an osteoprotegerin isolated from human or bovine milk or colostrum, or to an ingestible product made by adding to the food material, enteral composition or pharmaceutical composition an amount of osteoprotegerin isolated from human or bovine milk or colostrum, wherein the osteoprotegerin includes a glycosylation pattern giving rise to a polypeptide having a molecular weight of approximately 130 kda. It appears that these claims are a product by process claim, where the determination of the patentability is based on the product itself, see MPEP 2113. Thus, claims 17, 19, 23, 24 and 28 read a food material, a pharmaceutical composition, or an ingestible product such as milk that contains osteoprotegerin with a glycosylation pattern giving rise to a molecular weight of approximately 130 kda.

D'Ostilio *et al.* teach human breast milk samples were obtained from eight healthy mothers, and milk samples were collected on days 1-6 post-partum and 1 month after delivery. (page 543, right column). Since the reference teaches using the same source (i.e., human breast milk from healthy mothers) for naturally occurring osteoprotegerin as the instant application (see US 2004/0137074, paragraph [0048]), it would be expected that human breast milk in the reference inherently contains the same osteoprotegerin (i.e., osteoprotegerin with a glycosylation pattern giving rise to a molecular weight of approximately 130 kda; claims 17, 19, 23, 24 and 28) as the instant invention.

Art Unit: 1656

***Conclusion***

6. Claims 17, 19, 23, 24 and 28 are rejected. It appears that claims 18, 20 and 25-27 are free of art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

September 21, 2009